Use Case Data Element	Data Elements from interviews	Description	Source	Source	Source	Source	SIG Decision
Use Case 1.5							
AE Start Date	Adverse Event Date	The date when the adverse event occurred.			Med-Watch	COH, Duke, UPMC, Mayo	
	Date event reported to PI	The date the PI was notified of the adverse event.				UPMC	
	Date Investigator learned of the event	The date the investigator learned/was notified of the AE.				UCI, Mayo	
	Start Date of AE	The date the adverse event started.		AdEERS		UCI	
	Start Date of Primary AE	The date when the primary AE began.	DCP-AE Expedited Report Single agent v4.0, CSAERS	AdEERS - Course info			
MedDRA Code	MedDRA code that maps to the CTCAE term					COH	
CTC AE Category	Category	The high level classification in CTCAE containing the adverse event term.		**AdEERS**			

Use Case Data Element	Data Elements from interviews	Description	Source	Source	Source	Source	SIG Decision
	Toxicity Category	The category used to determine the toxicity.				UPMC	
AE Title	Adverse Event	The medical description of other adverse event using NCI CTCAE terminology.		**AdEERS**		COH, Mayo	
	Toxicity	The name of the toxicity.				UPMC	
	Name of AE	Name of the AE that prompted this report.				Duke	
Use Case 1.6							
Grade	Grade	The numeric indicator that describes the severity of an adverse event as defined by CTCAE v3.0 with a permissible value of 0 - 5.	DCP-AE Expedited Report Single agent v4.0, CSAERS	**AdEERS**		COH UPMC	
Expectedness						COH	

Use Case Data Element	Data Elements from interviews	Description	Source	Source	Source	Source	SIG Decision
Attribution	Attribution	Relation of the causality between the treatment modality and the specific adverse event.		**AdEERS**			
	Causality	Determine if the event was, for example, definite, probable, possible, or unrelated to the adverse event.				UPMC, Mayo	
	Relation of Event to Study (Drug/Device/ Procedure)	Determine if the event was related; possibly related; not related; or unknown to the study.				COH, UCI, Duke	
Study Relatedness						from WebBoard	
AE Stop Date	End Date of AE	The date the adverse event ended.		AdEERS			

Use Case Data Element	Data Elements from interviews	Description	Source	Source	Source	Source	SIG Decision
Intervention		Choose the intervention that contributed to this AE. May be one or more		AERS			
Course #/ Cycle #							
Action						from WebBoard	
Outcome						from WebBoard	
Severity	Hospitalization or prolonging of hospitalization	Was hospitalization or a prolongation of hospitalization required as a result of the adverse event.	DCP-AE Expedited Report Single agent v4.0, CSAERS	AdEERS			
	Seriousness of the Event	Determines the seriousness of the event such as Death, Hospitalization, or Other (specify).				UCI, Duke, Mayo	

Use Case Data Element	Data Elements from interviews	Description	Source	Source	Source	Source	SIG Decision
	Event Severity Classification	Determine if the severity of the event was serious unexpected or moderate unexpected.				UPMC	